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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/685,744	10/14/2003	Robert F. Rioux	267/296 (01-402)	6134

23410 7590 11/29/2006

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EXAMINER	
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ART UNIT	PAPER NUMBER
3739	

DATE MAILED: 11/29/2006

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/685,744
Filing Date: October 14, 2003
Appellant(s): RIOUX ET AL.

Michael J. Bolan
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed September 5, 2006 appealing from the Office action mailed March 15, 2006.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

6,071,280	Edwards	6-2000
6,241,710	VanTassel	6-2001
4,512,768	Rangaswamy	4-1985

6,503,225 Kirsch 1-2003

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-4 and 6-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards (U.S. Pat. No. 6,071,280) in view of VanTassel (U.S. Pat. No. 6,241,710).

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards (U.S. Pat. No. 6,071,280) in view of VanTassel (U.S. Pat. No. 6,241,710) and further in view of Rangaswamy (U.S. Pat. No. 4,512,768).

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards (U.S. Pat. No. 6,071,280) in view of VanTassel (U.S. Pat. No. 6,241,710) and further in view of Kirsch (U.S. Pat. No. 6,503,225).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4 and 6-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al (U.S. Pat. No. 6,071,280) in view of VanTassel et al. (U.S. Pat. No. 6,241,710 B1).

Regarding claim 1, Edwards et al. disclose an apparatus for delivering electrical energy to tissue within a patient, comprising:

a tubular member 12 comprising a proximal end 14, a distal end 16 having a size for insertion into a body of a patient, and a lumen extending from the distal end towards the proximal end (Fig. 2); and

a needle 20 comprising a distal portion extending at least partially from the lumen and terminating in a tissue-piercing distal tip, the distal portion comprising an electrically conductive material, thereby providing an electrode through which electrolytic fluid may flow for delivering electrical energy to tissue surrounding the distal portion (col. 9, ln. 64-66, col. 10, ln. 12-16, and Figs. 13-15).

The claim differs from Edwards et al. in calling for the distal portion of the needle tip to comprise a porous material. VanTassel et al., however, teach a needle 2, wherein the distal portion comprises porous sintered stainless steel to allow fluid to flow through pores in the walls of the needle shaft (col. 5, ln. 21-29, col. 5, ln. 41-45, and Fig. 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the distal portion of the needle of Edwards et al. from porous sintered stainless steel in view of the teaching of VanTassel et al. as an obvious alternate way of allowing fluid to flow through the walls of the needle shaft that is known in the art.

Regarding claim 2, Edwards et al. disclose the apparatus of claim 1 in view of VanTassel et al. Edwards et al. also disclose that the distal portion of the needle comprises stainless steel (col. 8, ln. 29-30). The claim differs from Edwards et al. in calling for the distal portion to comprise specifically sintered stainless steel. VanTassel et al., however, teach a needle 2, wherein the distal portion comprises sintered stainless steel to allow fluid to flow through pores in the walls of the needle shaft (col. 5, ln. 21-29, col. 5, ln. 41-45, and Fig. 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the distal portion of the needle of Edwards et al. in view of VanTassel et al. from sintered stainless steel also in view of the teaching of VanTassel et al. as an obvious alternate way of allowing fluid to flow through the walls of the needle shaft that is known in the art.

Regarding claim 3, Edwards et al. disclose the apparatus of claim 1 in view of VanTassel et al. In addition, Edwards et al. disclose a needle, wherein the needle comprises a needle lumen extending from a proximal end of the needle to the distal portion. Since electrolytic fluid is introduced to the ablation site through an initial connection to a fluid source at the proximal handle 10, the needle 20 must inherently comprise a needle lumen extending from a proximal end of the needle to the distal portion (col. 10, ln. 12-16 and Figs. 1 and 14).

Regarding claim 4, Edwards et al. disclose the apparatus of claims 1 and 3 in view of VanTassel et al. In addition, Edwards et al. disclose the apparatus further comprising a source of electrolytic fluid coupled to the needle lumen for delivering electrolytic fluid to the distal portion of the needle. Since electrolytic fluid is introduced to

the ablation site through needle 20, one of the tubes attached to the handle 10 in Fig. 1 must inherently couple a source of electrolytic fluid to the needle lumen for delivering electrolytic fluid to the distal portion of the needle (col. 10, ln. 12-16 and Figs. 1 and 14).

Regarding claim 6, Edwards et al. disclose the apparatus of claim 1 in view of VanTassel et al. In addition, Edwards et al. disclose a needle 20, wherein the needle is movable relative to the tubular member 12 for at least one of retracting the distal portion into the tubular member and deploying the distal portion from the tubular member (col. 6, ln. 16-30, col. 9, ln. 55-65, and Figs. 11-15).

Regarding claim 7, Edwards et al. disclose the apparatus of claim 1 in view of VanTassel et al. In addition, Edwards et al. disclose a tubular member 12, wherein the tubular member comprises an electrically insulating sleeve 28 (col. 9, ln. 7-9 and Fig. 13.

Regarding claim 8, Edwards et al. disclose the apparatus of claim 1 in view of VanTassel et al. In addition, Edwards et al. disclose a plurality of needles 20 extendable from the lumen beyond the distal end of the tubular member 12, each needle comprising a distal tip for penetrating tissue (Figs. 11-13).

Regarding claim 9, Edwards et al. disclose the apparatus of claims 1 and 8 in view of VanTassel et al. Edwards et al. disclose that each of the plurality of needles comprises a distal portion comprising an electrically conductive and porous material in view of VanTassel et al. because if it is obvious to modify one needle, it is obvious to modify the plurality of needles. (See the preceding rejection of claim 1.) In addition,

Edwards et al. disclose an array of porous electrodes 20 through which electrolytic fluid may flow for delivering electrical energy to tissue adjacent the distal portions of the array of electrodes (col. 10, ln. 12-16 and Figs. 13-15).

Regarding claim 10, Edwards et al. disclose an apparatus for delivering electrical energy to tissue within a patient, comprising:

a tubular member 12 comprising a proximal end 14, a distal end 16 having a size for insertion into a body of a patient, and a lumen extending from the-distal end towards the proximal end of the tubular member (Fig. 2); and

an array of needles 20 extendable from the lumen beyond the distal end of the tubular member, each needle comprising a distal tip for penetrating tissue, at least one needle comprising a distal portion comprising an electrically conductive material, thereby providing a porous electrode through which electrolytic fluid may flow for delivering electrical energy to tissue adjacent the distal portion. (col. 9, ln. 64-66, col. 10, ln. 12-16, and Figs. 11-15).

The claim differs from Edwards et al. in calling for the distal portion of the needle tip to comprise a porous material. VanTassel et al., however, teach a needle 2, wherein the distal portion comprises porous sintered stainless steel to allow fluid to flow through pores in the walls of the needle shaft (col. 5, ln. 21-29, col. 5, ln. 41-45, and Fig. 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the distal portion of the needle of Edwards et al. from porous sintered stainless steel in view of the teaching of VanTassel et al. as an obvious

alternate way of allowing fluid to flow through the walls of the needle shaft that is known in the art.

Regarding claim 11, Edwards et al. disclose the apparatus of claim 10 in view of VanTassel et al. In addition, Edwards et al. disclose needles 20, wherein the needles are movable from a retracted configuration within the lumen to an extended configuration wherein distal portions of the needles extend beyond the distal end of the tubular member 12 (col. 6, ln. 16-30, col. 9, ln. 55-65, and Figs. 11-15).

Regarding claim 12, Edwards et al. disclose the apparatus of claims 10 and 11 in view of VanTassel et al. In addition, Edwards et al. disclose a plurality of needles 20, wherein the plurality of the needles have distal tips that extend different axial and radial distances from one another in the extended configuration (col. 7, ln. 34-54).

Regarding claim 13, Edwards et al. disclose the apparatus of claims 10 and 11 in view of VanTassel et al. In addition, Edwards et al. disclose that a distal portion of a plurality of the needles comprises an electrically conductive material defining an electrode (col. 6, ln. 20-21 and Figs. 14-15). The distal portion comprises a porous material in view of VanTessel et al. (See the preceding rejection of claim 10.)

Regarding claim 14, Edwards et al. disclose the apparatus of claim 10 in view of VanTassel et al. In addition, Edwards et al. disclose a source of conductive fluid connected to the infusion lumen of each needle comprising an infusion lumen. Since conductive fluid is introduced to the ablation site through needles 20, one of the tubes attached to the handle 10 in Fig. 1 must inherently connect a source of conductive fluid

to the infusion lumens of each needle comprising an infusion lumen (col. 10, ln. 12-16 and Figs. 1 and 14).

Regarding claim 15, Edwards et al. disclose the apparatus of claims 10 and 14 in view of VanTassel et al. In addition, Edwards et al. disclose a hub proximal to the distal end of the tubular member, the hub comprising a port connected to the source of conductive fluid, the hub communicating with each infusion lumen for delivering conductive fluid from the source of conductive fluid to each porous electrode. Since there are two lines connected to the handle 10 shown in Fig. 1, one must be connected to the RF generator, and the other must be connected to the source of conductive fluid. Therefore, since there is only one line that connects the source of conductive fluid to each of the electrodes, there inherently must be a hub as claimed to connect the source of conductive fluid to each infusion lumen for delivering conductive fluid to each porous electrode.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al. ('280) in view of VanTassel et al. ('710) and further in view of Rangaswamy (U.S. Pat. No. 4,512,768).

Regarding claim 5, Edwards et al. disclose the apparatus of claim 1, wherein the distal portion of the needle comprises a porous material in view of VanTassel et al. The claim differs from Edwards et al. in calling for the entire needle to comprise porous material. Rangaswamy, however, teaches a needle 42 with pores 44 around and along its entire length to provide for uniform fluid infusion along the entire length of the

inserted needle and not just at the end (col. 2, ln. 65 – col. 3, ln. 5 and Fig. 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the entire needle of Edwards et al. in view of VanTassel et al. from the porous sintered stainless steel of VanTassel et al. further in view of the teaching of Rangaswamy to provide for uniform infusion of the electrolytic fluid along the entire length of the inserted needle and not just at the end.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al. ('280) in view of VanTassel ('710) and further in view of Kirsch et al. (U.S. Pat. No. 6,503,225 B1).

Regarding claim 16, Edwards et al. disclose the apparatus of claims 10 and 14 in view of VanTassel et al. The claim differs from Edwards et al. in calling for a float valve connected to the source of conductive fluid for removing gases from conductive fluid being delivered from the source of conductive fluid to each porous electrode. Kirsch et al., however, teach a catheter medical device with a float valve 10 with hydrophobic membranes 50 connected at 28 to the source of conductive fluid (such as saline) for removing gases from the fluid being delivered from the source of the fluid to the internal site of treatment in order to prevent injury to the patient due to air embolism (col. 1, ln. 24-37, col. 4, ln. 9-14, col. 7, ln. 1-9, and Figs. 1-6. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have included in the apparatus of Edwards et al. in view of VanTassel et al. a float valve as in

claim 16, further in view of the teaching of Kirsch et al. to prevent injury to the patient due to air embolism during treatment.

(10) Response to Argument

VanTassel Not Analogous Prior Art

Regarding claims 1-4 and 6-15, applicant first argues that VanTassel is not analogous prior art that can be combined with Edwards because VanTassel is not in the field of the inventors' endeavor. On page 5 of the Brief, applicant asserts that the field of the inventors' endeavor is the ablative treatment of tumors, while VanTassel is concerned with the injection of medicaments into tissue.

In response, the examiner maintains that applicant is unduly limiting the field of applicant's endeavor to not encompass the full scope of the invention. While applicant may be concerned with the ablative treatment of tumors, it is clear from the top of page 3 of the Brief that applicant is also concerned with the basic field of delivering fluid from a needle into tissue. If this were not true, applicant would not have specified that the needle of independent claims 1 and 10 had to comprise a porous material to allow fluid to flow there through. Furthermore, electrode needles that simply deliver fluid are well-known in the art, so it appears that applicant is attempting to define over the prior art by claiming how the needle delivers the fluid – i.e. through the porous material of the needle.

Thus, the examiner maintains that the field of applicant's endeavor must also encompass delivering fluid from a needle into tissue. Since VanTassel is also

concerned with delivering fluid from a needle into tissue, the examiner maintains that VanTassel is analogous prior art and that the rejections are proper.

Applicant further argues that VanTassel is not analogous prior art because VanTassel is not reasonably pertinent to the particular problem with which the inventors were concerned. On page 5 of the Brief, applicant asserts that the problem with which the inventors were concerned was making therapeutic ablations more efficient, whereas VanTassel was concerned with providing a means for microinjecting controlled amounts of injectate to minimize leakage otherwise due to the rapid transfer of fluid.

Again in response, the examiner maintains that applicant is unduly limiting the scope of the problem with which the inventors were concerned. While applicant may be concerned with the ablative treatment of tumors, applicant is also merely trying to uniformly deliver fluid through a needle (pg. 2, ln. 7-15 and pg. 28, ln. 22 – pg. 29, ln. 2 of applicant's original specification). Likewise, VanTassel is concerned with trying to uniformly deliver fluid through a needle (Abstract, col. 2, ln. 42-49, and col. 4, ln. 51 – col. 5, ln. 2). Therefore, the examiner again maintains that VanTassel is analogous prior art and that the rejections are proper.

Any Suggestion to Modify Edwards in View of VanTassel is Lacking

Regarding claims 1-4 and 6-15, applicant argues that VanTassel does not suggest modifying the needle of Edwards to comprise porous sintered stainless steel. At the bottom of page 7 of the Brief, applicant further argues that because the teachings of VanTassel are irrelevant to tissue ablation, they cannot be fairly applied to Edwards.

In response, the examiner again maintains that applicant has unduly limited the nature of the problem to be solved by Edwards and VanTassel. By doing this, the examiner submits that applicant has overlooked that it is not necessary for the needle of VanTassel to ablate tissue in order to provide motivation to make the needle of Edwards from a porous material.

Edwards clearly teaches delivering fluid through pores in at least one needle (col. 10, ln. 12-16 and Figs. 13-15). Likewise, VanTassel teaches delivering fluid through pores in at least one needle (Abstract, col. 2, ln. 42-49, and col. 4, ln. 51 – col. 5, ln. 2). Since both Edwards and VanTassel are clearly concerned with delivering fluid through pores in at least one needle, one of ordinary skill in the art at the time the invention was made would have been able to reasonably apply the teaching of VanTassel to the device of Edwards. Furthermore, VanTassel teaches making the needle from porous sintered stainless steel in order to allow uniform fluid distribution (Abstract, col. 2, ln. 42-49, and col. 4, ln. 51 – col. 5, ln. 2). So to add further support, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the needle of Edwards from a porous material in view of the teaching of VanTassel in order to allow uniform fluid distribution.

It is further noted that at the top of page 8 of the Brief, applicant lists a series of advantages derived from making an electrode needle from a porous material. Applicant argues that VanTassel does not teach these advantages. In response to this argument, the fact that applicant has recognized other advantages which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the

differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Finally, it is noted that the needle electrodes of Edwards with discrete pores (Figs. 13-15) may still constitute a "porous material" in the broadest reasonable sense.

Regarding claim 5, it is noted that applicant's arguments have been directed solely at the rejection of independent base claim 1. Therefore, applicant's arguments with respect to claim 5 have been addressed in the preceding remarks.

Regarding claim 16, it is noted that applicant's arguments have been directed solely at the rejection of independent base claim 10. Therefore, applicant's arguments with respect to claim 16 have been addressed in the preceding remarks.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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